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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,053	09/26/2003	Arnold R. Leiboff	461.1005	7183
22846	7590	08/28/2006	EXAMINER	
BRIAN ROFFE, ESQ 11 SUNRISE PLAZA, SUITE 303 VALLEY STREAM, NY 11580-6170			HILL, LAURA C	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,053

Applicant(s)

LEIBOFF, ARNOLD R.

Examiner

Laura C. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 40-42, 44-59 and 66-79 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 9, 45-59, 69-77 and 79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-8, 10-17, 40-42, 44, 66-68 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/26/03, 9/16/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Species I and VI in the reply filed on 26 June 2006 is acknowledged. The traversal is on the ground(s) that Species I should be considered with Species VI since there are only minor differences recited (See Remarks page 13). This is not found persuasive because Species I (originally presented claims 1-7 and 66-68) require a sewing ring with a notch on the tubular portion of the body but did not require the notch be located *around the circumference* of the tubular portion as in Species VI (original claim 78).

The requirement is still deemed proper and is therefore made FINAL. Since claims 1-8, 10-17, 40-42, 44, and 66-68 have been amended to depend from and include the limitations of elected Species VI directed to claim 78 and these dependent claims only contain further limitations rather than distinct species, the aforementioned claims have been examined on the merits as discussed below.

Drawings

2. The drawings are objected to because they are informal and are difficult to read. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and

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where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Bowel Insertion Tube with Sewing Suture Ring.

Claim Language Interpretation

4. The "tubular body having a front end *adapted to* be inserted into the bowel" as recited on line 2 of claim 78 is interpreted to mean that the tubular body may be shaped in such a manner so as to be inserted into a bowel opening or any other type of naturally-occurring (e.g.: and not an opening caused by surgical intervention) body opening.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 78, 1, 5-7, 10, 12-17, 40-42, and 66-68 are rejected under 35

U.S.C. 102(b) as being anticipated by Gellman et al. (US 2001/0010008; herein

Gellman). Regarding claim 78 Gellman discloses an anchor implantation device 10 for introducing a bone anchor 22 transvaginally and driving it into the pubic bone (page 4, paragraph 0071); and a suture strand/sewing ring 54, 254 arranged circumferentially around a tubular body 12 and including a circumferentially extending notch 122 (page 4, paragraph 0075, figures 1, 15 and 31-33), whereby the sewing ring attaches to the body by passing a filament through the body and sewing ring (page 4, paragraphs 0075-0076).

Regarding claim 1 Gellman discloses the sewing ring 54, 254 is substantially circular and extends rearward of an inward end of a notch 122 (figures 1, 15 and 31).

Regarding claims 5-7 and 67 Gellman discloses a bone anchor/rolled bowel sheath 22 retained within notch/ridge 30 and wherein the ridge 30 circumferentially extends from an outer circumferential surface of tubular body 12 (page 5, paragraph 0089, figure 1).

Regarding claim 10 Gellman discloses a plastic or stainless steel compatible for insertion into the body (page 11, paragraph 0175). The method of forming the device (e.g. "injection molded") is not germane to the issue of patentability of the device itself. Therefore, this limitation has been given little patentable weight.

Regarding claim 12 Gellman discloses a distal end of the body 12 includes central bore/thread 52 for mating with a cap 58 (page 6, paragraph 101).

Regarding claims 13-15 Gellman discloses the body 12 proximal end has at least one cannula/triangular lip 44 to facilitate insertion of the tube and to prevent the opening from slipping off the body (page 6, paragraph 0096, figure 1).

Regarding claims 16-17 and 68 Gellman discloses the sewing ring 54, 254 is arranged rearward of the triangular lip and proximate a distal portion of the body 12 and formed monolithically with the body (figure 1).

Regarding claims 40-42 and 66 Gellman discloses the triangular lip 44 as discussed above with respect to claims 13-15. Gellman further discloses a side arm extending perpendicularly down from the inserter 252 (figure 15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al. (US 2001/0010008; herein Gellman) in view of Sheridan (US 3,777,761;

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herein 'Sheridan'). Regarding claim 8 Gellman discloses the bone anchor/rolled bowel sheath 22 as discussed above with respect to claim 5. Gellman *does not expressly disclose* the sheath is made of molded latex or silicone. **Sheridan** discloses a post-operative drainage tube 2 with elongate tubular member 4 having a distal end 6, proximal end 10, and closure cap 12 to be inserted into a body cavity such as an abdomen or chest (column 1, lines 18-23 and lines 29-32, column 2, lines 64-69), a suture strip/sewing ring 16, 20 arranged around the circumference of the tubular body 4 (column 3, lines 1-23), and a joint/bowel sheath 30 made of flexible water-proof plastic materials (column 3, line 47-column 4, line 4). Although Sheridan does not expressly disclose the plastic materials comprise silicon or latex, it is well known to those of ordinary skill in the art that both silicone and latex are flexible water-proof materials. One would be motivated to modify the bowel sheath of Gellman with the flexible bowel sheath of Sheridan for improved device ease of motion since the references disclose tubular bodies implanted into body orifices and having sewing ring/suturing attachment means. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the bowel sheath, thus providing a sheath made of silicone or latex.

Regarding claim 11 Gellman *does not expressly disclose* a transparent tubular body. **Sheridan** discloses tubular body member 4 is formed of a clear, transparent material (column 3, lines 10-12). One would be motivated to modify the plastic tube of Gellman with the transparent body material of Sheridan for improved monitoring of fluid egression since the references disclose tubular bodies implanted into body orifices and

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having sewing ring/suturing attachment means. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the tubular body, thus providing a transparent body.

7. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al. (US 2001/0010008; herein Gellman). Gellman discloses a triangular lip 44 as discussed above with respect to claim 13. Gellman does not expressly disclose a plurality of triangular lips. However, it would have been obvious to one of ordinary skill in the art to modify to have made multiple lips, as opposed to a single, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura C. Hill
Examiner
Art Unit 3761

LCH



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER





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EXAMINER

ART UNIT	PAPER
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